Disc O Tech

When Orthopaedics Meets Hi-Tech

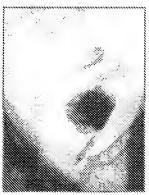
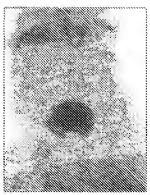
CONFIDENCE™

Confidence Cement System

For Treatment of VCF

Introduction of Putty-Like Bone Cement With Full Confidence



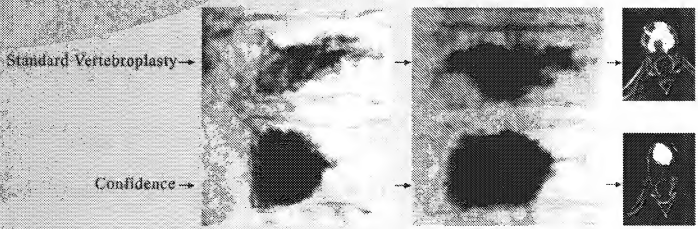
Confidence Cement Introduction

FOR TREATMENT OF VCF'S

INTRODUCTION OF PUTTY-LIKE BONE CEMENT WITH FULL CONFIDENCE

A putty-like, radio-opaque acrylic bone cement (PMMA) and innovative Hydraulic Delivery System that ensures safe and immediate cement introduction

- No liquid phase - immediate putty-like phase.
- Long working time in a constant putty-like state.
- Minimized risk of extravasation, emboli and neurological complications.
- Introduction through an 11/13 gauge Introducer Needle.
- Controlled, continuous & directional cement introduction.



Confidence safely fills the vertebral body in a contained, controlled manner, whereas standard vertebroplasty fills the vertebral body in an uncontrolled manner.

Safe Procedure

Percutaneous procedure
Directional cement introduction through a beveled tip or a side-firing Introducer Needle
Precise, controlled and continuous cement introduction that can be stopped at any time

User-Friendly, Fast & Easy Handling

Short cement preparation and handling time
Minimized radiation exposure of physician's hands
Reduced procedure time
Disposable

Novel Manual Hydraulic Delivery System

Ergonomic operating handle
Provided pre-filled with sterile water
Long extension tube enables the physician to keep his hands outside the X-ray field
Transparent Cement Reservoir
Optional multi-use Foot Pedal System

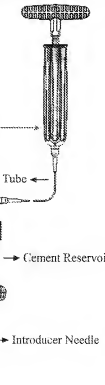
Variety of Introducer Needles

11 or 13 gauge Introducer Needles
Introducer Needle with larger inner lumen
4" (100mm) or 6" (150mm) long Needles
Proprietary Biopsy Needles

Confidence Elite Introducer Needle

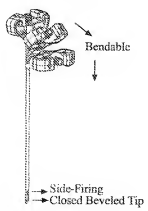
Enables Needle introduction, biopsy collection and directional cement introduction in a single step for minimizing the risk of leakage
The Needle is bendable and facilitates an easy AP view without interference with the C-arm imaging device

Option 1:
MANUAL SYSTEM

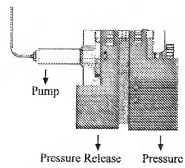


Pump System

SUPER NEEDLE



Option 2: PEDAL SYSTEM



SYSTEM KITS

Confidence Cement System	9750002
Confidence Plus Cement System	9750003

ACCESSORIES

Introducer Needle - 11G/4" (100mm)	9750430
Introducer Needle - 11G/6" (150mm)	9750420
Biopsy Needle - 13G	9750224

Introducer Needle - 13G/4" (100mm)	9750580
Introducer Needle - 13G/6" (150mm)	9750590
Biopsy Needle - 15G	9750222

Elite Introducer Needle 11G Side Ports, Beadable & Biopsy Style	9750223

www.disc-o-tech.com

For more details, including complete indications, contraindications, warnings and precautions refer to the Instructions for Use.

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Rev: 04, 7/06
PSA-0107501

Patents are pending

Caution: Federal law (U.S.A.) restricts this device to sale by or on the order of a physician

CE 0086

Disc O Tech

Disc Orthopaedic Technologies, Inc.

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URL: www.disc-o-tech.com
Tax ID #: 13-414-4324

Contact Information:
Ronny Barak – Chief Operating Officer
Dvir Sherpsky - Technical and Clinical Inquiries
Dasha Bezoza – Billing Inquiries and Customer Service

Terms:
Net 30

Monday, July 31, 2006

CONFIDENCE™
For Treatment of VCFs

David Cook
Harbor Radiology
2018 Port Provance Place
Newport Beach, CA 92660

Dear David:

We received your request for information on the CONFIDENCE™ Cement System. We thank you for your interest.

CONFIDENCE™ for treatment of VCFs: ready-to-use, putty like, radio-opaque acrylic cement (PMMA) and proprietary delivery system that ensures safe and immediate cement introduction is used for the fixation of pathological fractures of the vertebral body during vertebroplasty or kyphoplasty procedures. Using *CONFIDENCE™* minimizes risk of extravasation, emboli and neurological complications.

As per your request, enclosed is literature about the CONFIDENCE™ Cement System concept.

If you would like more information or would like to have a meeting with one of our representatives, please call (800) 936-6006.

Most Sincerely,

Dasha Bezoza
Office Manager
Disc Orthopaedic Technologies, Inc.
dasha@disc-o-tech.com

(800) 936-6006

Enclosure

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 21 2006

Disc-O-Tech Medical Technologies, Inc.
c/o Jonathan S. Kahan, Esq.
Hogan & Hartson, L.L.P.
555 Thirteenth Street, NW
Washington, DC 20004-1109

Re: K060300
Trade/Device Name: Confidence High Viscosity Bone Cement
Regulation Number: 21 CFR 888.3027
Regulation Name: PMMA Bone Cement
Regulatory Class: II
Product Code: NDN
Dated: May 19, 2006
Received: May 19, 2006

Dear Mr. Kahan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indication for Use

510(K) Number (if known): K060300

Device Name: Confidence High Viscosity Bone Cement

Indication for Use:

The Disc-O-Tech Confidence High Viscosity Bone Cement is indicated for the fixation of pathological fractures of the vertebral body using vertebroplasty or kyphoplasty procedures. Painful vertebral compression fractures may result from osteoporosis, benign lesions (hemangioma), and malignant lesions (metastatic cancer, myeloma).

Prescription Use √ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K060300

CONFIDENCE™ CEMENT DELIVERY SYSTEM

INSTRUCTIONS FOR USE

INDICATIONS FOR USE

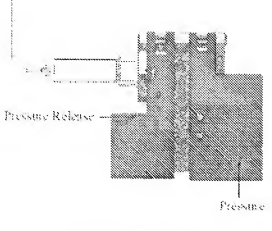
The Confidence Cement Delivery System is intended for percutaneous delivery of bone cement, during vertebroplasty/kyphoplasty procedures.

SYSTEM DESCRIPTION

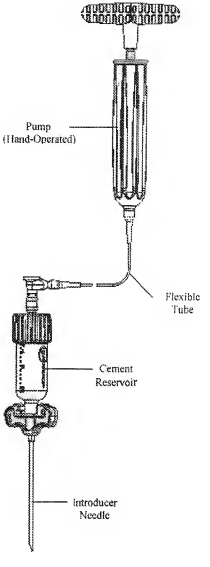
The Confidence Cement Delivery System comprises a 15 ml cement reservoir (barrel), a manual hydraulic pump (either hand-, or foot-operated, provided pre-filled with sterile liquid) and a flexible tube, connecting the reservoir to the pump.
The system accessory instruments include 10, 11 or 13 Gauge introducer needle, combined of a cannula and stylet, to provide for percutaneous access into the vertebral body and material introduction. Arrows on the needle handle indicate the bevel orientation. The accessories may include also a set of cement mixing tools – a mixer and a reservoir adapter (to assist in cement reservoir filling). The reservoir adapter may optionally be provided already connected to the cement reservoir.

PACKAGING, HANDLING, AND STERILIZATION

The sterile-supplied components of the Confidence Cement Delivery System are sterilized by ethylene oxide, gamma radiation, or steam, and are intended for single use.
The sterile packaging should be inspected for damage and expiration date prior to use. Do not use in any case of suspicion that sterility has been compromised.
The foot-pedal (optionally provided) is supplied non-sterile, and is intended for multiple use. No special maintenance is required, and handling (*e.g.*, cleaning) of the foot-pedal shall be as done with other operation room similar devices (*e.g.*, fluoroscopy device foot-pedal). Use enzymatic based detergents or soap for cleaning.



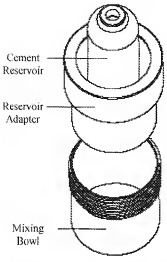
Foot-Pedal-Operated Pump



The Confidence CDS

ADVERSE EVENTS

Potential adverse events include, but are not limited to, events arising from the percutaneous introduction of surgical devices into the body, *e.g.*, infection and hematoma, and the possibility of cement leakage.



Components Assembly for Transferring the Cement into Reservoir

WARNINGS AND PRECAUTIONS

1. The surgeon should be familiar with the principles and technique of vertebroplasty/kyphoplasty, including possible side effects and limitations, and with the physiology and pathology of the selected anatomy.
2. Proper handling and storage of the system is mandatory. Damage or alterations may cause defects, which could become the focal point for failure.
3. The sterile packaging shall be inspected for visible damage prior to use. Do not use if damage is suspected.
4. Do not use sterile supplied items if the expiration date is overdue.
5. Do not re-sterilize the sterile-supplied, single use items! All parts that are provided non-sterile shall be handled per Packaging, Handling and Sterilization Section.
6. Verify firm connection of the system components prior to cement introduction.
7. Always cancel the pressure within the system when cement introduction is no longer desired (by counter-clockwise rotation of pump handle, or by pressing the pressure release pedal).
8. Prior to bone cement introduction, carefully verify there is no air in the system.
9. When a foot-pedal is used – verify correct operation of the system and the intactness of the thread connecting to the pump body.
10. Do not treat more than two vertebrae with one Confidence Cement Delivery System.

PROCEDURE

1. Prepare the operation site according to standard surgical techniques and hospital procedures.
2. Under fluoroscopy, insert the introducer needle (cannula and stylet assembly) up to the surgical site (the introducer needle tip should be positioned about 5 mm from the vertebra anterior wall).
3. For foot-pedal operated pump:
   Thread the pump to the foot-pedal connector.
4. Prepare the cement following its manufacturer's instructions.
5. Fill the reservoir with the cement, according to the following instructions.
   i. Turn the reservoir cap counter-clockwise until it is fully unscrewed.
   ii. Transfer the cement into the reservoir.
   Note: When using the mixing accessories provided with the Confidence Cement Delivery System – if the reservoir adapter is provided unconnected to the cement reservoir, screw the reservoir adapter to the reservoir; after mixing the cement, screw the reservoir adapter to the mixing bowl. This will result in cement entering the reservoir. Once cement transferring is completed, disconnect the reservoir from the adapter.
   iii. Thread the reservoir cap and hand-tighten it thoroughly to the reservoir.
6. Connect the flexible tube (which is attached to the pump) to the proximal end of the reservoir.
7. Remove the stylet from the cannula.
8. Attach the reservoir distal tip to the cannula.
9. Rotate the hand-operated pump handle clockwise in order to introduce the cement (or – press the green pedal of the foot-operated system). Use fluoroscopic imaging throughout the procedure to verify and monitor adequate cement flow.
   Note: The volume of the cannula may reach about 1 ml (for a 10 Gauge cannula of about 15 cm length).
10. Stop cement introduction by rotating the hand-operated pump handle counter-clockwise, until force-free handle rotation is achieved (about three full turns). If a foot-pedal is used, press the red pedal to cease cement introduction.
11. When the required amount of cement has been introduced, stop cement introduction as indicated in step 10, and disconnect the reservoir from the cannula.
12. Remove the cannula using oscillating motions, prior to cement setting.

Patents are pending

Web Site: www.disc-o-tech.com

CE 0086

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E-Mail: [illegible]

US AUTHORIZED REPRESENTATIVE
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NJ 08831, U.S.A.
Tel: 1-800-9366006, 1-609-3954172
Fax: 1-609-395417
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EC AUTHORIZED REPRESENTATIVE
MEDNET GmbH
Borkstrasse 10, 48163 Münster, Germany

Caution: In the U.S.A., federal law restricts this device to sale by or on the order of a physician.

CONFIDENCE™ HIGH VISCOSITY BONE CEMENT

INSTRUCTIONS FOR USE

INDICATIONS

Disc-O-Tech CONFIDENCE High Viscosity Bone Cement is indicated for the fixation of pathological fractures of the vertebral body using vertebroplasty or kyphoplasty procedures. Painful vertebral compression fractures may result from osteoporosis, benign lesions (hemangioma), and malignant lesions (metastatic cancers, myeloma).

DESCRIPTION

Disc-O-Tech CONFIDENCE High Viscosity Bone Cement is polymethylmethacrylate (PMMA) radiopaque bone cement. Its package includes two sterile components: a sachet containing the powder polymer and an ampoule containing the liquid monomer.

COMPOSITION

Powder Component (20 gr)

Polymethylmethacrylate	69.39 % w/w
Barium sulfate	30.07 % w/w
Benzoyl peroxide	0.54 % w/w

Liquid Component (9.2 gr)

Methylmethacrylate	98.5 % v/v
N,N-dimethyl-p-toluidine	1.5 % v/v
Hydroquinone	20 ppm

CONTRAINDICATIONS

- Coagulation disorders, or severe cardiopulmonary disease.
- Spinal stenosis (>20 % by retropulsed fragments).
- Patient clearly improving on medical therapy.
- Prophylaxis in metastatic or osteoporotic patients with no evidence of acute fracture.
- Non-pathological, acute traumatic fractures of the vertebra.
- Vertebral plana (collapse >90 %).
- Compromise of the vertebral body or the walls of the pedicles.
- Unstable vertebral fractures due to posterior involvement.
- Haemorrhagic diathesis.
- Cases of active or incompletely treated infection.
- Hypersensitivity to one of the components of the product.

WARNINGS

- Carefully read and understand the instructions prior to use.
- The operator should have specific training and experience to be thoroughly familiar with the properties, handling characteristics and application of the product and percutaneous cement delivery.
- Disc-O-Tech does not recommend a surgical technique; it is the responsibility of the physician to determine the appropriateness of the CONFIDENCE cement and specific technique for each patient.
- The duration of the working phases depends on the ambient temperature and those of the components, but also on the degree of hygrometry of the operating block. A high temperature reduces hardening time. A low temperature extends this time.
- Strictly adhere to aseptic principles and techniques. Deep wound infection is a serious postoperative complication and may require total removal of the embedded cement. Deep wound infection may be latent and not manifest itself even for several years postoperatively.
- Hypotensive reactions have occurred between 10 and 165 seconds following application of bone cement. They have lasted from 30 seconds to 5 minutes. Some patients have progressed to cardiac arrest. The patient should be monitored carefully for any change in blood pressure during and immediately following the application of cement.

- Always check the condition of the liquid before performing the procedure. Do not use monomer if the liquid component shows any sign of thickening or premature polymerization.
- Methylmethacrylate (MMA) can cause hypersensitivity in susceptible persons, which may result in anaphylactic response.
- The liquid component has caused dermatitis in its handling and mixing. Follow handling, mixing and preparation instructions carefully.
- Caution should be used during the mixing of the two components to prevent excessive exposure to the concentrated vapors of the monomer, which may produce irritation of the respiratory tract, eyes and possibly the liver.
- Do not allow the liquid component to come into contact with rubber or latex gloves. The liquid component is a powerful lipid solvent. Should contact occur, the gloves may dissolve and tissue damage may occur. Wearing a second pair of gloves may diminish the possibility of hypersensitivity reactions.
- Do not allow personnel wearing contact lenses to be near or involved in mixing of the cement.
- The completion of polymerization occurs in the patient and is an exothermic reaction with considerable release of heat. According to ISO 5833 standard, the temperature can be as high as 95°C. The long-term effect of the heat produced along with the resulting tissue damage is not known.
- Maintain patient positioning until the end of the polymerization process to obtain proper fixation. For proper fixation, 1-2 hours or longer may be required, as determined by the patient's medical condition and the attending physician.
- Use appropriate imaging techniques to verify correct needle placement, absence of damage to surrounding structures, and appropriate location of the injected bone cement. Use imaging, such as fluoroscopy, to assess the ability of the vertebra to contain the injected bone cement.
- Leaks can occur upon injection if the needle is mislocated in a vein or if unseen micro-fractures are prevalent.
- If bone cement is seen outside of the vertebral body or in the circulatory system during the procedure, immediately stop the injection.
- Inadequate fixation or unanticipated postoperative events may affect the cement bone interface and lead to micro-motion of the cement against the bone surface. A fibrous tissue layer may develop between the cement and the bone. Long-term follow-up is advised for all patients on a regularly scheduled basis.
- Do not re-sterilize. Single patient use only. Sterile only if package is unopened and undamaged.
- Do not use this product after the expiration date printed on the package.
- Not recommended in patients that do not exhibit a pathological condition, such as primary or secondary osteoporosis or a tumor, which would impair the ability of the patient to heal using conservative treatment methods.
- The use in pregnant woman and children has not been established.
- The long-term effects of the bone cement in the spine have not yet been established.

PRECAUTIONS FOR USE

- Only qualified physicians, trained in percutaneous cement delivery should use this bone cement.
- The surgeon must familiarize himself with the CONFIDENCE operating technique, and must adhere to it strictly. It is therefore advisable to abide by the preparation times recommended. If the instructions leaflet is ignored, undesirable effects may arise.
- A thorough preoperative check-up of the patient must be carried out before the operation.
- During the application of CONFIDENCE cement, radiological control is essential so that the operator can follow the progress of the filling and stop the procedure if the slightest leakage of cement is detected.
- Adequately ventilate the operating room to eliminate as much monomer vapor as possible.
- The liquid monomer is highly volatile and flammable. Ignition of monomer fumes caused by the use of electrocautery devices in surgical sites near freshly implanted bone cements has been reported.
- The insertion of a foreign body into the tissues increases the normal risk of infection associated with surgery during the postoperative period.
- Allow the mixed bone cement to set before disposing of it with other clinical waste. The polymer component may be disposed of in an authorized waste facility. The liquid component can be evaporated under a well-ventilated hood by an inert material and transferred in a suitable container for disposal.

ADVERSE EFFECTS

It is histologically agreed that the cement may lead directly or indirectly to the following complications:

- Cardiac arrest, cerebrovascular accident, pulmonary embolism, myocardial infarction, sudden death, transient reduction in arterial pressure, short-term cardiac conduction disturbances.

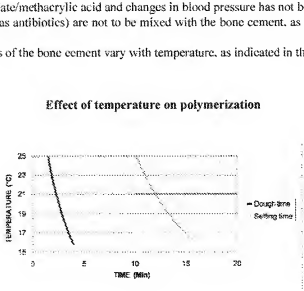
Other potential adverse events associated with vertebroplasty procedure include:

- Pneumonia, intercostal neuralgia, collapse of a vertebra adjacent to the one injected due to an osteoporotic disease, pneumothorax, cement extrusion into soft tissue, fracture of a pedicle,
- Rib fracture in patients with diffuse osteopenia, especially during thoracic vertebroplasty procedures, due to the significant downward force exerted during needle insertion,
- Compression of the spinal cord with paralysis or loss of feeling,
- Cement leakage between intervertebral discs,
- Deep or superficial wound infection,
- Fistula,
- Hematoma,
- Hemorrhage,
- Hypertension,
- Hypotension,
- Thrombophlebitis,
- Pyrexia,
- Hematuria,
- Dysuria,
- Bladder fistula,
- Transitory increase in pain due to heat released during polymerization,
- Nerve entrapment and dysphagia due to extrusion of the cement beyond its intended application,
- Adhesion and structure of the ileum due to heat released during polymerization.

IMPORTANT PHYSICIAN INFORMATION

- Percutaneous vertebroplasty procedures should only be performed in medical settings in which emergency decompressive surgery is available.
- Adverse reactions affecting the cardiovascular system have been attributed to bone cement. Recent data indicate that the monomer undergoes rapid hydrolysis to methacrylic acid, and that a significant fraction of the circulating methacrylate is in the form of the free acid rather than the methyl ester. Correlation between changes in circulating concentrations of methylmethacrylate/methacrylic acid and changes in blood pressure has not been established.
- Additives (such as antibiotics) are not to be mixed with the bone cement, as this will alter cement properties.
- The setting times of the bone cement vary with temperature, as indicated in the graph below.

Effect of temperature on polymerization



PATIENT INFORMATION

The patient should be informed by the physician of the potential consequences of the factors mentioned in the paragraphs contraindications and adverse effects, that is, those liable to hinder the success of the operation, as well as possible complications which may arise. The patient should also be informed of the measures to be taken to diminish the possible consequences of these factors.

INSTRUCTIONS FOR USE

Preparation of the CONFIDENCE High Viscosity Bone Cement

1. Open the sachet with care and pour all the powder into a suitable clean, dry, sterile mixing bowl made of an inert material (such as the Confidence Mixing Tools).
2. Open the ampoule - do not break the ampoule over the bowl (risk of glass splinters).
3. Pour all the liquid onto the powder and mix thoroughly until homogeneous mixture is obtained.

Introduction of the CONFIDENCE High Viscosity Bone Cement

- The CONFIDENCE cement is ready for use immediately following its components mixing.
- The introduction of the cement should be performed under continuous radiological control.
- The introduction should be stopped when the operator judges the vertebral filling to be satisfactory, or when a risk of leakage of cement appears.
- The CONFIDENCE cement should be introduced through a vertebroplasty needle, and using cement delivery system intended for percutaneous delivery of cement, such as the CONFIDENCE Cement Delivery System (carefully read the cement delivery system Instructions for Use prior to use).

With operating block and material temperature of 20°C, the different phases are as follows:

- Mixing: 30 – 60 seconds.
- Filling the delivery system: 1 – 2 minutes.
- Application phase: 7 minutes (following components mixing)
- Hardening: 4 minutes.

STERILIZATION

The liquid in the ampoule is sterilized by ultra-filtration, and the ampoule blister is sterilized by ethylene oxide. The powder, in a double sachet, is sterilized by gamma rays at 25 kGy.
Before using, check the protective wrapping carefully to ensure that it has not suffered any damage which could compromise its sterility.
When removing the product from its wrapping make sure to adhere to asepsis rules.
The cement is supplied sterile, ready for use in the operating block.
Do not re-sterilize. Single patient use only. Sterile only if package is unopened and undamaged.
Do not use after the expiry date.

PACKAGING AND STORAGE

Designation	Powder	Liquid
CONFIDENCE Cement	20 g	9.2 g

The cement should be stored unopened in its original packaging, in a dry, clean place away from light, at a maximum temperature of 25°C.

Disc-O-Tech Medical Technologies Ltd.
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Fax: 972-9-9548939
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Web Site: www.disc-o-tech.com

Patents are pending

Caution: In the U.S.A., federal law restricts this device to sale by or on the order of a physician.

Disc O Tech

Products Spine

CONFIDENCE CEMENT SYSTEM

B-TWIN EXPANDABLE SPINAL SYSTEM

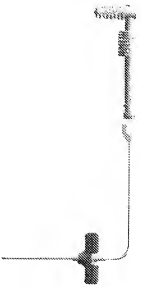
SKy BONE EXPANDER SYSTEM

HI-VISCO FLOW

CERVICAL B-TWIN EXPANDABLE SPINAL SYSTEM

HI-VISCO FLOW

The Hi-Visco Flow is a high viscosity cement injection system. The injection of high-viscosity cement reduces the risk of leakage associated with liquiform cement. Furthermore, thicker cement can be precisely situated in the bone. The Hi-Visco Flow is user friendly, simple and safe.



Precise High Viscosity Cement Injector

- Enables the use of high viscosity, paste-like, cement.
- Safe, controlled and continuous injection.
- Eliminates the exposure of the physicians hands.
- Percutaneous procedure.
- Fast and easy handling.
- Pressure resistant.

Safe Procedure

- Enables the use of high viscosity, paste-like, cement.
- Minimized risk of cement extravasation.
- Immediate pressure reduction that stops the cement flow completely.
- Extension tube with 90° bending elimenates exposure of the physician's hand.

Controlled and Continuous Cement Injection

- Large volume reservoir assures continuous injection.
- Precise volume control, one turn advances 0.5cc of cement.
- Graduated cement reservoir for volumetric

measurement.
- Radiolucent cannula for better cement flow visualization.
- No plunger distortion assures consistent injection.

Fast and easy handling

- User-friendly.
- Ergonomic design.
- Easy cannula insertion and removal.
- Supplied sterile.
- Disposable.

Pressure resistant

- Robust system.
- Allows longer working times.
- Extension tube made of Peek.
- Low torque needed for high viscosity cement injection.

Caution: Federal law (U.S.A) restricts this device to sale by or on the order of a physician.
US Patent No. 6, 127, 597. Other patents are pending.

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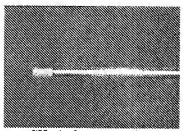
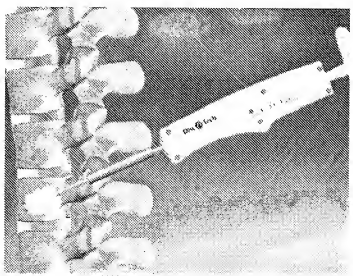
SKy BONE EXPANDER SYSTEM

The SKy Bone Expander is a polymer device, intended for kyphoplasty. The SKy Bone Expander is inserted into the collapsed vertebra in a reduced device configuration of 4 in diameter. Once positioned within the vertebra, it is expanded to up to 14 mm or 16 m in height and its pre-designed expanded size in a controlled manner. Once optimal vert height and void are achieved, the SKy Bone Expander is removed and void filler is injected into the void.



SKy before expansion

SKy after expansion



SKy Bone Expander System

FEATURES

- Creates a defined void in a controlled manner.
- Provides maximal user control over the extent of device expansion.

- Gradual expansion to pre-defined configuration avoids breaching of the vertebral walls.
- Increases vertebral height.
- Assures safe and localized injection of bone filler in the void.
- Enables percutaneous approach.
- Available in different sizes.

PRINCIPLES OF OPERATION

- The SKy Bone Expander is inserted percutaneously into the collapsed vertebra.
- The physician can control the placement and extent of SKy expansion.
- Controlled manual SKy expansion results in void creation and vertebral body reconstruction.
- The SKy is manually contracted and withdrawn from the vertebra.
- The created void is then filled with cement or bone filler material.
- The result is a reconstructed, strengthened vertebra.

INDICATION

The SKy Bone Expander System is intended for use in the treatment of thoracic and lumbar spine vertebral body compression fractures at levels T5-L5.

Case 1: SKy Bone Expander during procedure

Collapsed Vertebral Body Pre-Op | SKy Expansion | Expanded SKy

Not available in the USA

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